19 June 2009

EEB and BUND (Friends of the Earth Germany) response to the EU Public consultation "Scientific Hearing on Nanotechnology"

The issues surrounding the wide spectrum of potential risks and possible benefits associated with the rapid advance of modern nanotechnologies are of high interest for the European Environmental Bureau and BUND from the standpoint of environmental civil society groups. These include the current realities of nanotechnological hazards, their impact vis-a-vis nanotech-risks and benefits, and the consequent repercussions on the public, society and the environment. Our central idea is that the technological risks must be properly and timely communicated to the public (along with the benefits) to ensure the democratic, responsible and safe development of this emerging technology. We also consider that beyond a public hearing on nanotechnologies and related risks, the European Commission should host a public debate on technological innovation as such in the context of sustainability (sustainable production and consumption).

Meanwhile, EEB demands that no further market introduction be allowed for products containing manufactured nanomaterials which could lead to exposure of consumers or uncontrolled release in the environment. Such a restriction should be put in place until appropriate impact and safety assessment tests are developed and appropriate nano-specific risk assessment carried out and mandated that provide scientific proof that these materials and products are adequately safe to human health and the environment. Those products already on the market should be should be removed from commercial circulation until proven safe.

1. Identification of any possible topics which have not been covered in the opinions from the relevant EU Risk Assessment Committees and Bodies

1.1 Environmental impacts of nanomaterials have not been addressed in depth

For an adequate risk assessment to be conducted it is critical to have information on the amount of engineered nanomaterials (ENMs) dispersed in the environment as well as have the understanding of their environmental impacts. The Royal Commission on Environmental Pollution states: "Difficulties also arise because the form in which materials make their way into the environment might not be the same as that encountered during manufacture. Many free nanoparticles agglomerate and aggregate in the natural environment, forming larger structures that may have different toxicological properties to those exhibited by original nanoform"[1]. EU Scientific Opinions barely addresses the results of relevant ecotoxicological studies and do not discuss the broader environmental impacts of nanomaterials even when there is data on ecotoxicology available.

1.2 Lifecycle approach in risk assessment

Nanomaterial lifecycle assessments – including manufacturing, transport, product use, and end-of-life management – need to be undertaken to understand the potential hazards and assess the probability and severity of adverse effects of ENMs. This approach has also been requested by the UK Royal Society and the Royal Academy of Engineering[2].

[1] Royal Commission on Environmental Pollution 2008: Novel Materials in the Environment: The case of nanotechnology.

2 The Royal Society and the Royal Academy of Engineering, (2004).Nanoscience and nanotechnologies: opportunities and uncertainties, pp. 85-88.

1.3 Toxicological and exposure data for many emerging nanomaterials are missing
The lack of toxicological and exposure data for many emerging nanomaterials is a critical gap for risk assessment. Furthermore, there is little to no specific information about exposures to engineered nanomaterials although the potential for human exposure could be significant in workplaces or via consumer products. Together, these gaps contribute to uncertainty about whether or not nanomaterials are ‘‘new’’ and whether or not they pose ‘‘novel’’ and significant risks to the environment and human health, which is key information for enacting preventive statutes as well as regulations.

1.4 Assessment of actual human and environmental exposure
Little to nothing is known about actual and long term human exposures to engineered nanomaterials in real workplaces or the environment, or what levels of exposures are likely to be harmful[3]. If available, information on exposure comes from industry, which is not verified by independent regulatory or scientific bodies. In the EU Scientific Opinions no data can be found regarding the current and prospective exposure of humans and the environment.

1.5 Migration of ENMs
Like other substances, nanomaterials could migrate from materials in which they are supposed to be “bound”, leading to consumer and environmental exposure. EFSA stated in its opinion on “The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety” that “(…) few studies indicates that some ENM may migrate while others do not. Migration is likely dependent on the type of ENMs and FCM and no general conclusion can be drawn.” Therefore more data on nanomaterials fate in the environment is urgently necessary to determine and study the possible exposure routes and affected environmental media.

1.6 Next generation of ENMs[4]
EU Scientific Committees have not yet examined the safety challenges and ethical implications of next generation nanomaterials, which may range from relatively simple active nanomaterials, such as drug delivery systems already entering the market, to complex interactive nanotechologies for human enhancement and use in synthetic biology. According to the Washington based Woodrow Wilson Centre for Scholars future generations of nanomaterials are likely to have wide-ranging impacts and will hardly be manageable within the current scope of legislation[5]. It is therefore high time for the Commission to begin assessing the safety challenges next generation nanomaterials will pose.

1.7 Combined effects of exposure to nanomaterials
EU Scientific Committees have so far failed to consider the combined effects of exposure to a nanomatierials “cocktail”. It has also not been studied how ENMs interact with each other once they have entered the human biological system or have been released in the environment . The joint impact of various ENMs is thus to be researched before any final conclusions on risks are made.

The behaviour of agglomerates formed from ENMs have also to be assessed more comprehensively. EFSA itself states that “It can be assumed that ENM agglomerates break up under certain conditions that occur in food, feed, the gastro intestinal tract and biological tissues.”

1.8 Standard Definition of Nanomaterials still missing
It is crucial to agree and adopt a standard definition of nanomaterials which will be used in all

[3] Nowack B, Bucheli TD (2007) Occurrence, behavior and effects of nanoparticles in the environment. Environmental Pollution 150:5–22.
[4] Also see: Royal Commission on Environmental Pollution 2008: Novel Materials in the Environment: The case of nanotechnology.
[5] Davies: Oversight of Next Generation Nanomaterials, 2009, http://pewnanotech-project.us/news/archive/davies4/

scientific opinions and will be the basis of EU legislation of ENMs. This has not been achieved to date and is detrimental to the scientific acceptance of the Risk Assessment Committees' opinions. Environmental civil society groups have proposed an extensive definition[6] that brings clarity and coherence on key aspects of nanomaterials with focus on:
- Size being defined from 0.3nm to 300nm;
- Substances having nanomaterial-like properties to be included, even though they fall beyond the official size range;
- All nanomaterials to be included in regulation including aggregates and agglomerates, and not just those that are insoluble or bio-accumulative.

2. Identification of what are, according to current scientific knowledge, the main potential risks that could emerge from the use of nanomaterials in the future

2.1 Human toxicity

Many of the properties that make the benefits of nanomaterials can also make them more likely to react with tissues in the body and cause cellular and tissue damage. A large body of research associates existing nanomaterials in the environment, such as fine and ultrafine particulates produced incidentally via fossil fuel combustion, with adverse public health effects such as **respiratory problems, cardiovascular diseases, and/or increased mortality**[7],[8].

A growing number of studies on engineered nanomaterials show that some of these materials can have detrimental biological effects. For example, **nanoscale titanium dioxides** used in sunscreens and cosmetics have been associated with **pulmonary effects such as lung inflammation, pulmonary damage, and fibrosis** in animal studies and related effects in vitro [9],[10],[11].

Many different types of carbon nanotubes, which have fibrous structures similar to that of asbestos, are used in electronics, pharmaceuticals, and a variety of other applications; **some forms of carbon nanotubes have been associated with oxidative stress, cytotoxicity, inflammation, granuloma formation, and fibrogenesis** in in vitro and in vivo studies[12].

Fullerenes are used in catalysts, copolymers and composites, lubricants, drugs and drug delivery systems, cosmetics, health care products, and sporting goods. Due to their antioxidant properties, they show promise as treatments for cancer, AIDS, and bacterial infections, but some studies suggest that they **can cause DNA damage**[13].

Quantum dots, nano-sized particles used or being developed for use in electronics, biomedical imaging, and surveillance, are typically made of cadmium or lead, well-known toxins. Toxicological and pharmaceutical studies suggest that protective coatings of quantum

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[6] Friends of the Earth "Discussion paper on nanotechnology standardisation issues", June 2008: http://nano.foe.org.au/node/344.

[7] Nel A, Xia T, Madler L, Li N (2006) Toxic potential of materials at the nano level. Science 311(5761):622–627.

[8] Oberdorster G, Stone V, Donaldson K (2007) Toxicology of nanoparticles: a historical perspective. Nanotoxicology 1(1):2–25.

[9] Bermudez E, Mangum JB, Asgharian B, Wong BA, Reverdy EE, Janszen DB, Hext P, Warheit DB, Everitt JI (2002) Long-term pulmonary responses of three laboratory rodent species to subchronic inhalation of pigmentary titanium dioxide particles. Toxicological Sciences 70:86–97 and Bermudez E, Mangum JS, Wong BA, Asgharian B, Hext PM, Warheit DB, Everitt JI (2004) Pulmonary responses of mice, rats, and hamsters to subchronic inhalation of ultrafine titanium dioxide particles. Toxicological Sciences 77:347–357.

[10] Grassian VH, O'Shaughnessy PT, Adamcakova Q-Dodd, Pettibone JM, Thorne PS (2007) Inhalation exposure study of titanium dioxide nanoparticles with a primary particle size of 2 to 5 nm. Environmental Health Perspectives 115(3):397–402.

[11] Long TC, Tajuba J, Sama P et al (2007) Nanosize titanium dioxide stimulates reactive oxygen species in brain microglia and damages neurons in vitro. Environmental Health Perspectives 115(11):1631–1637.

[12] Donaldson K, Aitken R, Tran L, Stone V, Duffin R, Forrest G, Alexander A (2006) Carbon nanotubes: a review of their properties in relation to pulmonary toxicological and workplace safety. Toxicological Sciences 92(1):5–22.

[13] Sayes CM, Gobin AM, Ausman KD, Mendez J, West JL, Colvin VL (2005) Nano-C60 cytotoxicity is due to lipid peroxidation. Biomaterials 26:7587–7595.

dots **can degrade in light and oxidative conditions, releasing these metals into cells and organisms and causing toxic effects[14]**.
There are numerous other types of nanomaterials currently in production, most of which have not been studied for toxicity.

2.2 Adverse environmental effects

Engineered nanomaterials used widely for environmental applications will eventually end up in the environment. Moreover, the increasing number of nanomaterials used in consumer products and construction materials are likely to eventually find their way into air, water, and soil through waste streams when these products are discarded and/or through wear and tear[15].
A small but growing number of studies have been done to date to assess fate and transport of engineered nanomaterials. Brumfiel[16] reported that fullerenes dispersed in water are poorly absorbed by soils, which may allow **absorption by terrestrial invertebrates**. A more recent study suggests that negatively charged aggregates of C60 **fullerenes may be stable in aqueous environments[17]**. Similarly, a recent study on **multi-walled carbon nanotubes** shows that they **can remain stable in water** for up to a month[18]. These studies raise concerns about potential transport of these materials downstream from their emissions.
Concerns have also been raised about potential effects on wildlife and ecosystems of nanomaterials released into the environment. Fortner[19] and Brayner[20] showed that **when micro-organisms are exposed to varying concentrations of nanomaterials** (e.g., zinc oxide, buckyballs), their **growth and metabolism are inhibited.** Others have shown that some nanomaterials **can cause hatching delays, deformities, and acute toxicity** in zebrafish and/or zebrafish embryos[21], [22] and **respiratory distress, organ pathologies, and other physiological effects** in rainbow trout[23], [24]. A unique study on plants suggests that **some nanomaterials may inhibit seed germination and root growth[25]**. One of the only food-chain studies to date[26] showed that **nano-sized zinc oxide and fullerenes are more toxic to algae** than larger particles and can be transferred to higher organisms along the food chain.

2.3 Microbial resistance to antibiotics

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[14] Hardman R (2005) A toxicological review of quantum dots: toxicity depends on physico-chemical and environmental factors. Environmental Health Perspectives 114(2):165–172.
[15] Blaser SA, Scheringer M, MacLeoda M, Hungerbu¨hler K (2007) Estimation of cumulative aquatic exposure and risk due to silver: contribution of nano-functionalized plastics and textiles. Science of the Total Environment 390:396–409.
[16] Brumfiel G (2003) Nanotechnology: a little knowledge. Nature 424:246–248.
[17] Duncan LK, Jinschek JR, Vikesland PJ (2008) C60 colloid formation in aqueous systems: effects of preparation method on size, structure, and surface charge. Environmental Science and Technology 42(1):173–178.
[18] Hyung H, Fortner JD, Hughes JB, Kim JH (2007) Natural organic matter stabilizes carbon nanotubes in the aqueous phase. Environmental Science and Technology 41(1):179–184.
[19] Fortner J, Lyon DY, Sayes CM, Boyd AM, Falkner JC, Hotze EM, Aleman LB, Tao YJ, Guo W, Ausman KD, Colvin VL, Hughes JB (2005) C60 in water: nanocrystal formation and microbial response. Environmental Science and Technology 39:4307–4316.
[20] Brayner R, Ferrari-Iliou R, Brivois N, Djediat S, Benedetti MF, Fievet F (2006) Toxicological impact studies based on Escherichia coli bacteria in ultrafine ZnO nanoparticles colloidal medium. Nano Letters 6(4):866–870.
[21] Cheng J, Flahaut E, Cheng SH (2007) Effect of carbon nanotubes on developing zebrafish embryos. Environmental Toxicology and Chemistry 26(4):708–716.
[22] Griffitt RJ, Weil R, Hyndman KA (2007) Exposure to copper nanoparticles causes gill injury and acute lethality in zebrafish (Danio rerio). Environmental Science and Technology 41:8178–8186.
[23] Federici G, Shaw BJ, Handy RD (2007) Toxicity of titanium dioxide nanoparticles to rainbow trout (Oncorhynchus mykiss): gill injury, oxidative stress, and other physiological effects. Aquatic Toxicology 84(4):415–430.
[24] Smith CJ, Shaw BJ, Handy RD (2007) Toxicity of single walled carbon nanotubes to rainbow trout (Oncorhynchus mykiss): respiratory toxicity, organ pathologies, and other physiological effects. Aquatic Toxicology 82(2):94–109.
[25] Lin DH, Xing BS (2007) Phytotoxicity of nanoparticles: inhibition of seed germination and root growth. Environmental Pollution 150(2):243–250.
[26] Luo J (2007) Toxicity and bioaccumulation of nanomaterial in aquatic species. Journal of the U.S. SJWP.

The usage of nano silver in higher quantities in a wide range of consumer products could cause resistance of harmful microbes to the nano substance and perhaps to silver in its macro form as well. Given that a large number of harmful bacteria has already become resistant to many antibiotics, it is essential to preserve the effectiveness of silver for use as an anti microbial substance in medical applications for future generations.

3. Identification of further issues to be discussed at the hearing

3.1 Gaps in Awareness, Communication, and Training

Low capacity of policy making staff and meager public awareness and training related to nanotechnology issues, along with potential communication gaps between producers and users of nanomaterials and the risk regulators, are likely to play critical roles in how proactively any problems with nanomaterials that might arise are handled. Communicating risk thus needs to be given a priority in the public debate on nanotechnologies to ensure an informed and active participation of various stakeholder groups.

3.2 Risk assessment tools for new technologies

Development of tools for sustainability assessment of new technologies, including risk assessment for their more systematic use in both research and product development is urgently needed. These should also be used in policy developments on innovation and eco-innovation, and sustainable industrial policy in the EU.